K082280
p1/2

OCT 0 8 2008

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Mary Kruitwagen
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-4932
Fax: 978-685-5624
Email: mary.kruitwagen@philips.com

This summary was prepared on July 31, 2008.

2. The names of the subject devices are the Philips SureSigns VM1 Patient Monitors and SureSigns VS2 Vital Signs Monitor.

3. The trade names of the devices are the SureSigns VM1 Patient Monitors (VM1) and the SureSigns VS2 Vital Signs Monitor.

4. The common usual name is multi-parameter patient monitor

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description	Applicable Subject Devices
Circulatory System Devices	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)	VS2, VM1
	870.1110, II	DSJ	Alarm, Blood Pressure	VS2
	870.1110, II	DSK	Computer, Blood Pressure	VS2
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive	VS2
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm	VS2, VM1
	870.2700, II	DQA	Oximeter	VS2, VM1
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector	VM1
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical	VS2
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,	VM1

6. The modified devices are substantially equivalent to previously cleared Philips device, SureSigns VM Series Patient Monitors and SureSigns VS3 Patient Monitor marketed pursuant to K052707 and K080495.

7. The modifications are as follows:

    - Introduction of the VM1 Patient Monitor (a subset of the predicate VM Series devices)
    - Introduction of the VS2 Vital Signs monitor (a subset of the predicate device VS3)
    - Modification of the predicate VS3 device to include the optional wireless bridge interface to transmit patient data records to an electronic medical record system.

8. The subject devices have the same intended use as the legally marketed predicate device. The SureSigns VS2 Vital Signs monitor and the SureSigns VM1 are for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitors may be used in transport situations within a healthcare facility. The addition of the wireless functionality to the predicate VS3 does not change the intended use or indications for use.

9. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design as the predict device. The composition of the VS2 and the VM1 materials are different than the predicate device, however are made of a material previously used in other medical devices. The chemical composition of the subject devices has changed but is the same as material used in other predicate devices. The energy source of the subject device the VS2 is an external power supply, while the VM1 will use a power supply that is the same as the predicate device. The VS2 and the VM1 both can run on battery power with batteries similar to the predicate devices.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VM1 Patient Monitors and SureSigns VS2 Vital Signs monitor and the modification to the SureSigns VS3 Vital Signs Monitor meet all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Philips Medical Systems
c/o Ms. Mary Kruitwagen
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810

Re: K082280
Trade/Device Name: SureSigns VS2 (reference numbers: 863079,863080; 863081, 863082); SureSigns VM1 (reference number: 863078) SureSigns VS3 (reference number: 863069; 863070, 863071, 863072, 863073, 863074)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: II
Product Code: MHX
Dated: August 8, 2008
Received: August 11, 2008

Dear Ms. Kruitwagen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

per Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082280

Indications for Use

510 (k) Number (if known): _____

Device Name: SureSigns VS2 (reference numbers: 863079, 863080, 863081, 863082)
SureSigns VM1 (reference number: 863078)
SureSigns VS3 (reference numbers: 863069, 863070, 863071, 863072, 863073, 863074)

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082280

Page ___ of ___